DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 16

Apotex Corp.
Attention: Marcy Macdonald
50 Lakeview Parkway, Suite 127
Vernon Hills, IL 60061

Docket No. 99P-0510/CP 1

Dear Ms. Macdonald:

This is in response to your petition filed on March 12, 1999, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Ketorolac Tromethamine Injection 30 mg/mL, 5 mL multiple-dose vials, total drug content 150 mg. The listed drug products to which you refer in your petition are Toradol® (Ketorolac Tomethamine Injection) 30 mg/mL, 1mL and 2 mL syringes manufactured by Hoffman LaRoche, Inc.

We have reviewed your petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act) and have determined that it is approved. This letter represents the Agency's determination that an ANDA may be submitted for the above-referenced drug product.

Your request involves a change in strength (total drug content) from that of the listed drug products (i.e., from 30 mg/mL, 1 mL and 2 mL syringes to 30 mg/mL, 5 mL multiple-dose vials). The change you request is the type of change that is authorized under the Act.

Under Section 505(j)(2)(C)(i) of the Act, the Agency must approve a petition seeking a strength, which differs from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The Agency finds that the change in strength for the specific proposed drug product does not pose questions of safety or effectiveness because the uses, dose, and route of administration of the proposed drug product are the same as that of the listed drug products. The Agency concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug products.

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The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the Agency has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the Agency.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you contact the Director, Division of Bioequivalence, at (301) 827-5847 to determine the specific requirements for this drug product. During the review of your application, the Agency may require the submission of additional information.

The listed drug products to which you refer in your ANDA must be the drug products upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research